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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/833,096	04/04/97	NELSON R	

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EXAMINER
WITZ, J

ART UNIT	PAPER NUMBER
1651	

DATE MAILED:

08/04/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

08/833,096

Applicant(s)

Nelson et al.

Examiner

Jean C. Witz

Group Art Unit

1651



☒ Responsive to communication(s) filed on May 8, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-66 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☒ Claim(s) 22, 23, 34-43, 46-48, and 52-62 is/are allowed.

☒ Claim(s) 1-21, 24-33, 44, 45, 49-51, and 63-66 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed May 8, 1998 have been fully considered but they are not persuasive for the reasons set forth below.

### ***Priority***

2. Applicants' response sets forth the status of the priority documents; however, the specification should also be amended to show said status and Applicants are again requested to update the status of the applications listed for priority under 35 USC 120 in the specification.

### ***Claim Rejections - 35 USC § 112***

3. Claims 63-65 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising deproteinated fasting bear serum or urine and the fractions disclosed in the specification, does not reasonably provide enablement for a pharmacological composition comprising 24,25-dihydroxyvitamin D3 or a composition having a molecular weight of 100 or less. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the reasons of record.

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Applicants argue that because DBI is shown to contain D3, therefore D3 is responsible for the effect of DBI. However, such has not been shown. DBI contains other components which have not been identified and it is reasonable, since DBI is obtained from urine or serum, that it contains other components of molecular weight of 100 or less. There is no disclosure regarding these components and one of skill in the art would need to engage in undue experimentation to identify and assay each component to determine their activity.

4. Claims 1-21, 24-30, 44-45 and 63-66 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the claims, the phrase "chemistry similar to" also fails to distinctly describe the composition, as it is unclear to what similarities or what chemistry the phrase such that the metes and bounds of the claims are not clear. In the claims, it is unclear what is meant by the term "ursus-like". Further, the phrase "resembling the characteristics of a bear derived isolate" fails to distinctly describe the composition, as it is unclear what constitute "resembling" and a "bear derived isolate". In claim 1, it is unclear how a composition can "comprise" pharmacological properties. In claim 4, it is unclear what is meant by the phrase "at least one vital sign of behavioral modification substance"; further, it is not clear what is meant by the term "other substances". In claim 8, it is not clear what is meant by the phrase "chemistry similar to an isolate of whole blood or whole urine sample". In claims 10 and 11, the phrase "comprising chemistry similar to of the deproteinated urine or blood serum isolate of fasting bear" is unclear. In claim

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12, the phrase “comprising chemistry similar to a sample of whole blood or whole urine taken from a fasting black bear” is also unclear. In claim 13, it is unclear what is meant by the term “signature exhibited in the deproteinated isolate of urine or blood”. Claims 1-15 and 18 are deemed vague and indefinite as the claims are defined by functional language; the claims are defined by what the composition does and not by what it is. Further, comparisons by use of the phrase “comprising chemistry similar to” are vague as there is no way to determine the required characteristics of the compared “isolate”. It is unclear as to exactly what Applicants consider their invention. In claims 44 and 45, it is unclear what is comprised by the term “substance”.

### ***Double Patenting***

5. Claims 32-33, 49 and 51 remain rejected under 35 U.S.C. 101 as being a substantial duplicate of claims 31, 48 and 50, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicants argue that the claims are not the same because they are directed to different effects upon administration; however, as far as can be determined from the specification and the claim language, the compositions are the same. They are merely describing inherent effects.

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***Allowable Subject Matter***

6. Claims 22-23, 31, 34-43, 46-48 and 52-62 are allowed.

***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

8. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073. The examiner

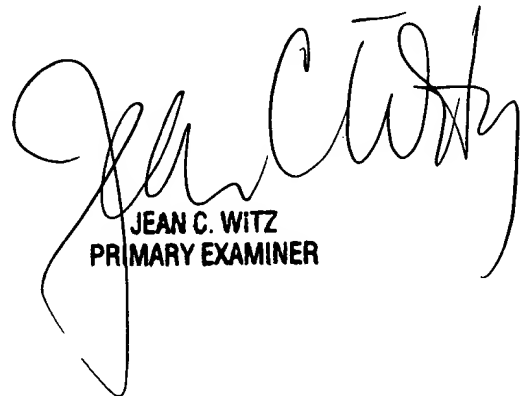
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can normally be reached on Monday through Thursday from 8:00 to 5:30. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

August 3, 1998



JEAN C. WITZ  
PRIMARY EXAMINER